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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,917	01/25/2002	Raj Chakrabarti	PU-0034	3743

7590

10/21/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

12

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/056,917

Applicant(s)

CHAKRABARTI ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,60-63 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,15-30,60-63 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-30, 60-63, 67-70) with sulfoxides as elected species in Paper No. 11 is acknowledged.
2. Claims 1, 2, 3, 5, 15-30, 60-63 and 67-70 readable on elected species in Group I are considered for examination in this office action. Claims 4, and 6-14 are withdrawn from consideration in view of the election (Paper No. 11). Claims 31-59 and 64-66 are cancelled (Paper No. 11).
3. The Information Disclosure Statement (Paper Nos. 7 and 8) filed on June 11, 2002 and March 5, 2003, respectively, have been entered and considered.
4. The instant application has filing date as January 25, 2002 and claims priority to provisional applications 60/264,935 filed on 1/30/2001, 60/298,166 filed on 6/14/2001 and 60/298,250 filed on 6/14/2001.

Claim Rejections - 35 USC § 112

- 5a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1, 2-3, 15-30, 60-63, 67-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims 1, 60 and 67 recite "R₂ is an unsubstituted" which is unclear and indefinite because it is not clear whether if R₂ is not a H or CH₃, does unsubstituted means no functional group is attached or R₂ is not present. Amendment to clarify the meets and bounds of the claims would obviate the rejection.

B. Claims 1, 2-3, 5-15, 60-63, and 67-70 are indefinite in the recitation of the term

Art Unit: 1637

'optionally' in the instant claims 1, 60, and 67. It is unclear whether any of the limitations which follow the term optionally are required limitations, i.e. are the further limitation followed by the term are 'optional' or critical. The metes and bounds of the claim are unclear.

5b. The following is the rejection made in the previous office action under 35 USC 112 first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2-3, 15-30, 60-63 and 67-70 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a composition, comprising one or more adjuvants comprising a formula comprising sulfoxides as set forth in the independent Claims 1, 60 and 67, wherein the composition further comprises polynucleotide replication reaction components. Further the dependent claims recite various modifications of the formula with various functional groups. This large genus of structural variants is represented in the specification by methyl, propyl, butyl, sulfoxides. Specification provides specific sulfoxide, i.e. tetramethelene sulfoxide. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or

attributes of the variants of the formula as set forth in the independent claims 1, 60 and 67 are disclosed. With regard to the various substitutions or modifications of the formula with various functional groups, this is insufficient to demonstrate identity of all specific compounds of the claimed invention. Instant claims are overly broad in the recitation of "comprising" since no guidance is provided as to which of the variant compounds would function as adjuvants in PCR amplification reaction. Further no information is given in the specification regarding a methodology to determine such common elements or attributes.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

It is noted that in *Fiers v. Sugano* (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after the compound has been isolated.

In the application at the time of filing, there is no record or description which

would demonstrate conception or written description of various sulfoxide compounds comprising modified by substitution with the disclosed functional groups and no correlative structure claimed product.

Accordingly, the specification does not provide a written description of the invention of claims 1, 2-3, 15-30, 60-63, 67-70.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2-3, 15-18, 20-30, 60-63, and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segev (USPN. 6,348,583) in view of Cheng (USPN. 5,512,462).

Segev teaches a compound (poly(ether-sulfoxide)) (adjuvant or cosolvent) comprising the formula of claims 1, 15, 60, and 67, wherein Segev teaches that the formula comprises R₁ as S; R₂ as H or CH₃; R₃ as C; and R₄, R₅ and R₆ as alkoxy or alkyl of length m, wherein m is

Art Unit: 1637

between 2 and 8 (see column 7, lines 38, 43, column 8, lines 42-43, referring the second formula structure, column 19, lines 56-67 referring formula structure);

Segev also teaches with regard to claim 2-3, 16-18, that the compound form a cyclic structure involving 5 carbon members (see column 8, lines 42-43 and structure, wherein a nucleobase group (purine or pyrimidine having cyclic structure is linked) (see column 9, lines 14-22) or a heterocyclic group is linked (see column 20, lines 50-56);

With regard to claim 20-21, Segev teaches that the compound is acyclic (see column 19, lines 56-67);

Segev teach that the compound could be used in PCR reaction, primer extension and sequencing (see column 25, lines 10-23), however Segev did not teach the PCR composition comprising a buffer, one or more template polynucleotides, nucleotide triphosphates (dNTPs), one or more polymerase enzymes.

Cheng teaches a PCR reaction composition of claims 1, 23-30, 60-63, 67-70, comprising (i) template DNA, dNTPs, a DNA polymerase (which include Tth DNA polymerase, Tli DNA polymerase) and buffer with cosolvents (see column 7, lines 65-67, column 8, lines 1-63, column 9, lines 1-67); (ii) cosolvents include glycerol, dimethylsulfoxide (DMSO), polyethylene glycol (see column 8, lines 65-67, column 9, lines 1-6); (iii) a kit comprising PCR reaction mixture along with cosolvents (DMSO, glycerol) (see column 36, lines 47-52); (iv) DMSO at a concentration of 0.5%- 5% (v/v) (see column 9, lines 26-41).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified and improved the use of the adjuvant or cosolvent of Segev with the inclusion of PCR components of Cheng in order to achieve a

Art Unit: 1637

sensitive and enhanced PCR composition as a whole. An ordinary practitioner would have been motivated to add the PCR components because Cheng taught that use of cosolvents influence the efficiency of amplification of the template by increasing the thermal stability of the DNA polymerase and reduces the loss of DNA polymerase activity during repeated high-temperature denaturation steps (see column 9, lines 2-7). Therefore, an ordinary artisan would have been clearly motivated to have modified the compound taught by Segev with the addition of PCR components to achieve efficient and improved PCR system.


Conclusion


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
October 17, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER